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EXAMINER
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ART UNIT	PAPER NUMBER
1636	

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8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/633,232	DIERYNCK ET AL.	
	Examiner	Art Unit	
	Terry A. McKelvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *01 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *11 and 18-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-10,12,13,15 and 16* is/are rejected.

7)☒ Claim(s) *7,14 and 17* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-10 and 12-20 (which, after election of azurin, is actually claims 1-10 and 12-17) in Paper No. 6, filed 11/1/02 is acknowledged. The traversal is on the ground(s) that (1) The restriction in terms of a specific apo metal binding protein provided no further information, explanation, classification, or reasoning, and that no prima facie showing of a serious burden was made because no explanation of different field of search, etc was provided. (2) It is also argued that the restriction requirement does not identify whether the restriction is between distinct inventions or an election between independent inventions, such as an election of species. (3) Finally, it is indicated that at least one claim recites only a nitrite reductase and that this feature of the restriction concerning a specific apo metal binding protein further deprives Applicants of an actual knowledge on the nature, characteristics and bounds of the purportedly asserted restriction. This is not found persuasive because of the following reasons.

(1) This assertion is incorrect that the restriction provided no further information, explanation, classification, or

reasoning, and that no prima facie showing of a serious burden was made because no explanation of different field of search, etc was provided. At page 3, first paragraph, the restriction indicated that each group is drawn to multiple inventions because of the use of different and distinct apo metal binding proteins which are (at least) patentably distinct for the reasons indicated. The applicant is also directed to MPEP 803.04, second paragraph: "Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to each other. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121." Different proteins, such as different apo metal binding proteins which are coded by independent and distinct genes, are equally independent and distinct for the same type of reasons. The serious burden was indicated at page 6, second paragraph, the search is different for each particular apo protein because the non-patent literature must be searched separately for each apo protein (within the context of the claimed invention, including the different limitations in the dependent claims), which is a serious burden for more than one independent and distinct apo protein. Art applicable to one apo protein is not necessarily applicable to another apo protein, because the reference may be

drawn to only one particular apo protein and not to the generic class of apo proteins. Thus, full examination of the invention drawn to all apo proteins would require a full search and analysis of each and every apo protein, which is clearly a burden for the limited time given for search and examination of an invention. Thus, the two parts of the restriction analysis was provided: reasons for distinctness and showing of burden.

(2) The distinctness of the inventions was indicated at page 3, first paragraph, although, as shown by MPEP 803.04, they are both distinct and independent.

(3) The applicant's point here is unclear. The nature of the restriction was clearly set forth. The claim drawn to nitrite reductase (and the rest of claims 18-20) are drawn to different apo proteins not elected and thus these claims are withdrawn as being drawn to a nonelected invention. They are still subject to linking claim practice, but because the generic claims that these claims depend upon are not allowable, the restriction stands.

The requirement is still deemed proper and is therefore made FINAL.

Claims 11 and 18-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or

linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

Claim Objections

Claims 1-10 and 12-17 are objected to because of the following informalities: claim 1 lacks the needed "and" between the last two members of the list. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8-9, 12-13, and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Griffiths et al (U.S. Patent No. 5,612,016).

Griffiths et al teach a method for detecting a site of disease (associated with a particular protein antigen, and thus it is a method of monitoring at least one target protein in a biological system) comprising injecting into a human subject

having a disease which produces or is associated with an antigen, an amount of a protein which is specific to the antigen and which is conjugated at a stereoprotected sulfhydryl group to a bifunctional chelating agent chelated with a (provided) metal capable of detection (column 4). This conjugate protein binds (links) to the antigen and emits a detectable signal, showing the location and amount of the antigen present in the cells and tissues of the biological system. At suitable times post-injection, the subject is imaged with a planar and/or spect imaging system (which quantitatively measures the signal and thus monitors the protein antigen based upon the signal observed) (column 16). The conjugate protein reads on "at least one apo metal binding protein" because the specification of the instant application (at page 7, paragraph 2) specifically defines an apo metal binding protein as "any protein or peptide that acquires a detectable color upon the binding of one or more metal ions or changes in color upon binding of a metal ion or an additional metal ion". The protein conjugate used in the method taught by Griffiths et al includes the use of nonradioactive metals selected for their useful physical properties (when chelated) such as fluorescence or phosphorescence (i.e., color), chosen from metals such as copper (columns 11-12). Proteins

useful for detecting include fibrin and various other human proteins, for example (column 6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-6, 8-10, 12-13, and 15-16 rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al. (U.S. Patent No. 5,612,016).

Griffiths et al teach a method for detecting a site of disease (associated with a particular protein antigen, and thus it is a method of monitoring at least one target protein in a biological system) comprising injecting into a human subject having a disease which produces or is associated with an antigen, an amount of a protein which is specific to the antigen and which is conjugated at a stereoprotected sulfhydryl group to a bifunctional chelating agent chelated with a (provided) metal capable of detection (column 4). This conjugate protein binds (links) to the antigen and emits a detectable signal, showing the location and amount of the antigen present in the cells and tissues of the biological system. At suitable times post-injection, the subject is imaged with a planar and/or spect imaging system (which quantitatively measures the signal and thus monitors the protein antigen based upon the signal observed) (column 16). The conjugate protein reads on "at least one apo metal binding protein" because the specification of the instant application (at page 7, paragraph 2) specifically defines an apo metal binding protein as "any protein or peptide that acquires a detectable color upon the binding of one or more

metal ions or changes in color upon binding of a metal ion or an additional metal ion". The protein conjugate used in the method taught by Griffiths et al includes the use of nonradioactive metals selected for their useful physical properties (when chelated) such as fluorescence or phosphorescence (i.e., color), chosen from metals such as copper (columns 11-12). Proteins useful for detecting include fibrin and various other human proteins, for example (column 6).

Griffiths et al do not specifically teach providing the "apo metal binding protein" to a cell in vitro, or using the method in other types of biological systems.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the conjugate protein detection of protein antigen method taught by Griffiths et al for the detection of any other type of antigen in any type of biological system in vitro or in vivo because Griffiths et al teach that it is within the ordinary skill in the art to use the conjugate protein for specifically determining the location of antigens and the use of reagents that bind to antigens and emit a detectable signal for measurement of the location and amount of the antigen, used in various types of biological systems in vitro and in vivo, is and was well known in the art (e.g., using radiolabeled or enzymatically labeled antibodies).

One would have been motivated to do so for the expected benefit of creating and using another type of reagent, a conjugate protein chelated with a detectable metal ion (as taught by Griffiths et al) to identify the location and quantity of any antigen of interest, in any biological system. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success in practicing the claimed invention.

Allowable Subject Matter

Claims 7, 14, and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. (Also, because claim 17 is drawn to nonelected inventions (pseudo-azurin, plastocyanin, and phytocyanin, these nonelected inventions need to be canceled because the generic linking claim 1 is not allowable for the reasons described above and thus the elected invention remains limited to azurin.)

Conclusion

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (703) 305-7213. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

January 27, 2003